

REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining be allowed.

Claim Amendments

Claim 69 has been amended to recite "selecting" in the preamble. Support for this amendment can be found, for example, in step (b) of claim 69.

No new matter has been added by this amendment. The Examiner is hereby requested to enter these amendments.

Applicants submit that all claim amendments presented herein or previously are made solely in the interest of expediting allowance of the claims and should not be interpreted as acquiescence to any rejections or ground of unpatentability. Applicants reserve the right to file at least one continuing application to pursue any subject matter that is canceled or removed from prosecution due to the amendments.

Interview

Applicants wish to thank Examiner Vandervegt for extending the courtesy of discussing this application with the undersigned over the phone and providing helpful suggestions on January 27, 2005. The subject of the interview were claim 69 and the rejection under 35 U.S.C. §112, second paragraph, for allegedly omitting essential steps. The undersigned argued that this rejection does not apply under MPEP §2172.01 and established case law. The Examiner suggested that the undersigned file a response containing the arguments made during the interview so that his supervisor can allow the claims. Applicants also wish to thank Examiners Nolan and Chan for helpful discussions regarding the same matter.

This Amendment and Reply is submitted in accordance with all of these discussions.

Election/Restrictions

The Office Action withdraws claims 74-78 as drawing to an unelected invention, and states that this invention “requires the search of naturally occurring antibodies that is not required for examination of the invention elected by original presentation” (page 2, numbered paragraph 1 of the Office Action). Applicants do not understand why naturally occurring antibodies have to be searched. Claims 74-78 are drawn to methods of identifying an antibody with an enumerated specificity, comprising providing candidate antibodies and determining their specificity. Since these are method claims, Applicants submit that naturally occurring antibodies do not have to be searched. Applicants further submit that examining these claims together with the other pending claims would not impose a serious burden on the part of the Examiner, as the other pending claims comprise similar steps.

Accordingly, Applicants respectfully request that claims 74-78 be examined in the present application.

Rejections Under 35 U.S.C. §112, Second Paragraph

A. The rejection of claims 63-66, 69-73 and 79 under 35 U.S.C. §112, second paragraph, as allegedly being incomplete for omitting essential steps, is respectfully traversed for the reasons set forth below.

Claim 63 is directed to a method for preparing an antibody or a fragment thereof that comprises the antigen binding site of the antibody, wherein said antibody binds to:

- (i) a mammalian IL-B30/p40 complex comprising an IL-B30 subunit (SEQ ID NO:2 or 4) and a p40 subunit of human or murine origin, or
- (ii) a fusion protein comprising the IL-B30 subunit and the p40 subunit;
said method comprising:
 - (a) raising an antibody to the IL-B30/p40 complex or a polypeptide that comprises at least 11 contiguous amino acids from the p40 subunit and at least 11 contiguous amino acids from the IL-B30 subunit,

- (b) determining the specificity of the antibody raised in step (a) using the IL-B30/p40 complex or fusion protein, and confirming that said antibody binds to the IL-B30/p40 complex or fusion protein; and
- (c) optionally preparing said fragment from said antibody.

The Office Action states that claim 63 does not comprise a step where the “raising” of the antibody occurs. Applicants disagree, as the step “raising an antibody” is where the “raising” occurs, and no essential steps have been omitted.

The Office Action cites MPEP §2172.01 to support this rejection. Pursuant to MPEP §2172.01, a claim which omits matter disclosed to be essential to the invention may be rejected under 35 U.S.C. §112, first paragraph, as not enabling. However, features which are merely preferred are not to be considered critical. MPEP §2163.08(c). In addition, MPEP §2172.01 further provides that a claim which fails to interrelate essential elements of the invention may be rejected under 35 U.S.C. §112, second paragraph, for failure to point out and distinctly claim the invention.

The step “raising an antibody” can be performed in a variety of ways that are well known in the art. It is established law that information that is well known in the art needs not be described in detail in the specification. MPEP §2163.II.A.2; *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986). Furthermore, the specific steps by which an antibody can be raised are not disclosed to be essential to the invention. Therefore, the detailed steps alleged to be missing are not the “essential” steps required under MPEP §2172.01, and they are properly not included.

The Office Action also alleges that there is “no connection between the ‘preparing an antibody’ in the preamble of the claim and the conclusion of ‘confirming that antibody binds.’ The statements are not linked by any rational, cohesive steps.” In fact, claim 63 clearly recites that the antibody is prepared by (a) raising an antibody, and (b) determining the specificity of the antibody raised in step (a) and confirming that said antibody binds. These are rational and cohesive steps regularly used to prepare antibodies. The Office Action does not mention these

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steps or address why they are not rational or cohesive. An explanation is respectfully requested if the Examiner believes that they are not rational or cohesive.

Since no essential steps are omitted, withdrawal of this rejection is respectfully requested.

B. The rejection of claims 69-73 and 79 under 35 U.S.C. §112, second paragraph, as being indefinite, has been obviated by correcting a typographical error. Thus, claim 69 has been amended to recite a "method of Selecting an antibody or fragment thereof" instead of "method of an antibody or fragment thereof". Accordingly, the amended claims are not indefinite, and withdrawal of this rejection is respectfully requested.

Conclusions

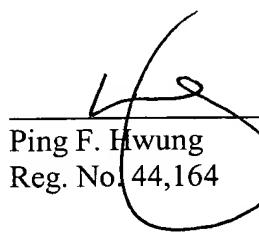
For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's objections and rejections are hereby requested. Allowance of the claims remaining in this application is earnestly solicited.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at (650) 839-5044.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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